

HCFA and the State administering agency.

(b) *Access to data and records.* A PACE organization must allow HCFA and the State administering agency access to data and records including, but not limited to, the following:

- (1) Participant health outcomes data.
- (2) Financial books and records.
- (3) Medical records.
- (4) Personnel records.

(c) *Reporting.* A PACE organization must submit to HCFA and the State administering agency all reports that HCFA and the State administering agency require to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates.

(d) *Safeguarding data and records.* A PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(e) *Confidentiality of health information.* A PACE organization must establish written policies and implement procedures to do the following:

(1) Safeguard the privacy of any information that identifies a particular participant. Information from, or copies of, records may be released only to authorized individuals. Original medical records are released only in accordance with Federal or State laws, court orders, or subpoenas.

(2) Maintain complete records and relevant information in an accurate and timely manner.

(3) Grant each participant timely access, upon request, to review and copy his or her own medical records and to request amendments to those records.

(4) Abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records, and other participant health information.

(f) *Retention of records.* (1) A PACE organization must retain records for the longest of the following periods:

- (i) The period of time specified in State law.
- (ii) Six years from the last entry date.

(iii) For medical records of disenrolled participants, 6 years after the date of disenrollment.

(2) If litigation, a claim, a financial management review, or an audit arising from the operation of the PACE program is started before the expiration of the retention period, specified in paragraph (f)(1) of this section, the PACE organization must retain the records until the completion of the litigation, or resolution of the claims or audit findings.

#### **§ 460.202 Participant health outcomes data.**

(a) A PACE organization must establish and maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure the organization's performance, including outcomes of care furnished to participants.

(b) A PACE organization must furnish data and information pertaining to its provision of participant care in the manner, and at the time intervals, specified by HCFA and the State administering agency. The items collected are specified in the PACE program agreement.

#### **§ 460.204 Financial recordkeeping and reporting requirements.**

(a) *Accurate reports.* A PACE organization must provide HCFA and the State administering agency with accurate financial reports that are—

(1) Prepared using an accrual basis of accounting; and

(2) Verifiable by qualified auditors.

(b) *Accrual accounting.* A PACE organization must maintain an accrual accounting recordkeeping system that does the following:

(1) Accurately documents all financial transactions.

(2) Provides an audit trail to source documents.

(3) Generates financial statements.

(c) *Accepted reporting practices.* Except as specified under Medicare principles of reimbursement, as defined in part 413 of this chapter, a PACE organization must follow standardized definitions, accounting, statistical, and reporting practices that are widely accepted in the health care industry.

(d) *Audit or inspection.* A PACE organization must permit HCFA and the State administering agency to audit or inspect any books and records of original entry that pertain to the following:

- (1) Any aspect of services furnished.
- (2) Reconciliation of participants' benefit liabilities.
- (3) Determination of Medicare and Medicaid amounts payable.

**§ 460.208 Financial statements.**

(a) *General rule.* (1) Not later than 180 days after the organization's fiscal year ends, a PACE organization must submit a certified financial statement that includes appropriate footnotes.

(2) The financial statement must be certified by an independent certified public accountant.

(b) *Contents.* At a minimum, the certified financial statement must consist of the following:

- (1) A certification statement.
- (2) A balance sheet.
- (3) A statement of revenues and expenses.
- (4) A source and use of funds statement.

(c) *Quarterly financial statement—(1) During trial period.* A PACE organization must submit a quarterly financial statement throughout the trial period within 45 days after the last day of each quarter of the PACE organization's fiscal year.

(2) *After trial period.* If HCFA or the State administering agency determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness, HCFA or the State administering agency may require a PACE organization to submit monthly or quarterly financial statements, or both.

**§ 460.210 Medical records.**

(a) *Maintenance of medical records.* (1) A PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards.

(2) The medical record for each participant must meet the following requirements:

- (i) Be complete.
- (ii) Accurately documented.
- (iii) Readily accessible.
- (iv) Systematically organized.
- (v) Available to all staff.
- (vi) Maintained and housed at the PACE center where the participant receives services.

(b) *Content of medical records.* At a minimum, the medical record must contain the following:

(1) Appropriate identifying information.

(2) Documentation of all services furnished, including the following:

(i) A summary of emergency care and other inpatient or long-term care services.

(ii) Services furnished by employees of the PACE center.

(iii) Services furnished by contractors and their reports.

(3) Multidisciplinary assessments, reassessments, plans of care, treatment, and progress notes that include the participant's response to treatment.

(4) Laboratory, radiological and other test reports.

(5) Medication records.

(6) Hospital discharge summaries, if applicable.

(7) Reports of contact with informal support (for example, caregiver, legal guardian, or next of kin).

(8) Enrollment Agreement.

(9) Physician orders.

(10) Discharge summary and disenrollment justification, if applicable.

(11) Advance directives, if applicable.

(12) A signed release permitting disclosure of personal information.

(13) Accident and incident reports.

(c) *Transfer of medical records.* The organization must promptly transfer copies of medical record information between treatment facilities.

(d) *Authentication of medical records.*

(1) All entries must be legible, clear, complete, and appropriately authenticated and dated.

(2) Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry.